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BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte PAUL C. DALY

Appeal 2009-013271
Application 09/670,781
Technology Center 1700

Decided: April 28, 2010

Before JEFFREY T. SMITH, LINDA M. GAUDETTE, and
JEFFREY B. ROBERTSON, *Administrative Patent Judges*.

GAUDETTE, *Administrative Patent Judge*.

DECISION ON APPEAL

Appellant appeals under 35 U.S.C. § 134(a) from the Examiner's decision finally rejecting claims 1-4, 6, 7, 10, 12, 13, 15-17, and 19-39 (Final Office Action, mailed Mar. 13, 2006, 1), the only claims pending in

the application. (Appeal Brief ("App. Br."), filed Mar. 20, 2009, 4.) We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM.

The following evidence is relied upon by the Examiner in support of unpatentability:

Koch	2,138,241	Nov. 29, 1938
Stockdale	3,390,766	July 02, 1968
Christine	3,414,414	Dec. 03, 1968
Meisner	3,478,489	Nov. 18, 1969
Beckers	3,654,746	Apr. 11, 1972
Lazure	4,054,207	Oct. 18, 1977
Corbic	4,165,594	Aug. 28, 1979
Bublitz	4,211,338	Jul. 08, 1980
Hendriks	4,597,242	Jul. 01, 1986
Lane	4,875,620	Oct. 24, 1989
Sharkey	5,429,262	Jul. 04, 1995

Honey-Flavored Liquid-Fructose in Single-Serving Packets, in Food Engineering 43-44 (1979) (hereafter "Food Engineering article").

Jean Carper, *Bit of Sugar May pacify Crying Babies, Study Says, in* Seattle Post-Intelligencer 1-3 (1990) (hereafter "Seattle Post-Intelligencer article").

Elliott M. Blass & Lisa B. Hoffmeyer, *Sucrose as an Analgesic for Newborn Infants, in* 87 Pediatrics No. 2, 215-218 (1991).

Marjorie Rice, *Nickel and Dime Stuff, in* San Francisco Examiner 003-005 (1991) (hereafter "The San Francisco Examiner article").

Study: Sugar Eases Newborns' Pain, in Wisconsin State Journal 4A (1991) (hereafter the "Wisconsin State Journal article").

Nissan Sugar Mfg, Has Started Marketing "Hot Joy," a New Syrup Exclusively for Hot Coffee and Tea for Use in the Winter Season, in New Food Products in Japan (1991) (hereafter "New Food Products in Japan").

Bonnie Stevens et al., *The Efficacy of Sucrose for Relieving Procedural Pain in Neonates – a Systematic Review and Meta-analysis, in* Scandinavian University Press 837-42 (1997) (hereafter "The Stevens 1997 article").

Bonnie Stevens et al., *The Efficacy of Developmentally Sensitive Interventions and Sucrose for Relieving Procedural Pain in Very Low Birth Weight Neonates, in* 48 Nursing Research No. 1, 35-43 (1999) (hereafter "The Stevens 1999 article").

Linda S. Franck, *The Use of Sucrose Analgesia to Relieve Procedural Pain in Neonates, in* 1 Children's Medical Ventures 1-3 (2000).

Applicant's Admission of Prior Art (hereafter "AAPA", Spec. 2-3).

The Examiner maintains (Examiner's Answer ("Ans."), mailed Apr. 21, 2009, 4-9), and Appellant requests review of (App. Br. 6), the following grounds of rejection:

1. claims 1-4, 6, 7, 10, 21, and 23-36 under 35 U.S.C. § 103(a) as obvious over Lazure (US 4,054,207) in view of the AAPA (Ans. 5) as evidenced by the Blass et al. article, the Stevens 1997 article, the Stevens 1999 article, the Franck article, further in view of Beckers (US 3,654,746), and Hendriks (US 4,597,242), Bublitz (US 4,211,338), further in view of the Seattle Post-Intelligencer article, Wisconsin State Journal article, further in view of the San Francisco Examiner article, New Food Products in Japan article, Food Engineering article, further in view of Koch (US 2,138,241), Corbic (US 4,165,594), Lane (US 4,875,620), Sharkey (US 5,429,262), Stockdale (US 3,390,766), Meisner (US 3,478,489), and Christine (US 3,414,414); and

2. claims 12, 13, 15-17, 19, 20, 22, and 37-39 under 35 U.S.C. § 103(a) as obvious over AAPA, the Stevens 1997 article, the Stevens 1999 article, the Franck article, the Seattle Post-Intelligencer article, the

Wisconsin State Journal article, in view of Lazure further in view of Beckers and Hendriks, Bublitz, further in view of Koch, Corbic, Lane, Sharkey, Stockdale, Meisner, and Christine, and further in view of the San Francisco Examiner article, New Food Products in Japan article, and the Food Engineering article.

With respect to the first ground of rejection, Appellant's arguments are directed to essentially the same limitations present in each of independent product claims 1, 23, and 29. (*See* App. Br. para. bridging 7-8.) Appellant does not present separate arguments in support of patentability as to any of the remaining claims (all of which are dependent claims), or a distinct sub-grouping of claims, subject to this ground of rejection. Accordingly, we decide the appeal as to all claims subject to the first ground of rejection on the basis of independent claims 1, 23, and 29. *See* 37 C.F.R. § 41.37(c)(1)(vii) (2009).

The second ground of "rejection employs all of the same references that are relied upon in the rejection of the article claims 1-4, 6, 7, 10, 21 and 23-36 above, but placed in a different order, in view of the fact that claims 12, 13, 15, 16, 22, 17, 19, 20, and 37-39 are method claims." (Ans. 8.) In traversing this ground of rejection, Appellant relies on the same arguments presented in connection with the first ground of rejection. (App. Br. 22-24.) Appellant also presents separate arguments directed to essentially the same limitation found in independent claims 12 and 17. (App. Br. 23.) Therefore, in addition to considering the patentability of claims 12, 13, 15-17, 19, 20, 22, and 37-39 on the basis of the arguments advanced in connection with the first ground of rejection, we also separately consider the patentability of

claims 12 and 17. Dependent claims 13, 15, 16, 19, 20, and 22 stand or fall with claims 12 and 17. *See* 37 C.F.R. § 41.37(c)(1)(vii) (2009).

Independent claim 1 reads as follows:

1. A packaged solution for use in conjunction with a planned medical procedure on a neonatal infant, comprising:

a cup-shaped container having a greater width than a depth and defining a cavity therein opening to a mouth;

a volume of a solution comprising sucrose and water within the cavity, wherein the solution comprises about 10% to about 50% sucrose with a remainder of the solution comprising water; and

a cover disposed over the mouth and sealing the solution within the cavity;

wherein the solution and an interior of the container are in an aseptic state.

(App. Br. 25, Claims Appx.)

Independent claims 23 and 29 are directed to "packaged solution assembl[ies]" which include "a cup-shaped container" and "a volume of solution comprising sucrose and water." (App. Br. 27-29, Claims Appx.)

Independent claim 12 is reproduced below:

12. A method for providing a solution for use in conjunction with a planned medical procedure on a neonatal infant, comprising:

preparing a solution comprising sucrose and water;

packaging the solution in single-use containers;

assembling a plurality of the single-use containers in a shipping container;

shipping the shipping container to an intended site of usage of the solution;

opening an individual, single-use container of the solution prior to the planned medical procedure;

administering a selected volume dose of the solution orally to the neonatal infant; and

discarding any residual solution within the opened, individual, single-use container after the planned medical procedure.

(App. Br. 26, Claims Appx.)

Independent claim 17 is directed to a "method of administering a solution to a neonatal infant" and includes a step of "discarding any residual solution with the container." Independent claim 37 is directed to a "method of producing a packaged solution assembly." (App. Br. 29, Claims Appx.)

Appellant presents several different arguments in support of his contention that the Examiner failed to establish a prima facie case of obviousness. (*See* App. Br. 8-13.) Appellant also relies on evidence of secondary considerations in support of non-obviousness. (*See* App. Br. 13-22.) For the reasons stated in the Examiner's Answer, we are not persuaded that the Examiner's factual findings and reasons are insufficient to support a prima facie case of obviousness under 35 U.S.C. § 103(a). Nor are we convinced that, taking into account Appellant's evidence, a preponderance of the evidence weighs in favor of non-obviousness. We provide further discussion of the following issues solely to emphasize that the Examiner's obviousness determination is consistent with the relevant case law:

1. In reaching a conclusion of obviousness, did the Examiner fail to take into account disclosure in Lazure which teaches away from the claimed invention?

2. Did the Examiner improperly rely on non-analogous art in reaching the conclusion of obviousness?

3. Did the Examiner fail to properly identify motivation to combine the references in the manner claimed?

4. Did the Examiner properly evaluate the facts established by Appellant's rebuttal evidence along with all the facts on which the prima facie case of obviousness was reached?

5. Taking into account Appellant's evidence of non-obviousness, including commercial success and long-felt need, did the Examiner err in concluding that a preponderance of the evidence weighs in favor of obviousness?

Issue 1: In reaching a conclusion of obviousness, did the Examiner fail to take into account disclosure in Lazure which teaches away from the claimed invention?

Appellant concedes that the use of unit dose medicinal containers was known in the art at the time of the invention (Reply Brief, filed Jun 22, 2009 ("Rep. Br."), 4), as evidenced by Lazure (App. Br. 8 (citing Lazure, col. 1, ll. 5-6)). Appellant further concedes that the applied prior art evidences it was known "to administer a sucrose solution to an infant." (Rep. Br. 4; AAPA, *e.g.*, Spec. 2, ll. 21-29.) Appellant argues, however, that "Lazure expressly teaches away from the [Examiner's] proposed placement of such sucrose solutions into Lazure's unit dose containers." (App. Br. 9.) In support of this argument Appellant asserts that "an appropriate unit dose

sucrose solution is so small, if it were placed in Lazure's container, . . . it would be difficult or impossible to transfer the entire unit dose . . . to a patient." (*Id.*) Appellant also argues that Lazure "teaches away from including greater than a unit dose of medicine in a container and . . . from administering less than the entire unit dose contents of the container." (App. Br. 23.) Appellant thus contends that the Examiner erred in finding that the applied prior art suggests addition of a solution of sucrose and water to a container as required by all the independent claims, and in finding that the applied prior art suggests a step of discarding residual solution as required by independent claims 12 and 17.

"A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant." *In re Gurley,* 27 F.3d 551, 553 (Fed. Cir. 1994).

As an initial matter, we note that Appellant has not explained why Lazure's disclosure should be construed as limited to containers of a size too large to accommodate a unit dose sucrose solution. However, even if Lazure's disclosure is so limited, Appellant has not convincingly argued that the ordinary artisan would have been discouraged from adjusting the size of Lazure's container to accommodate a unit dose of sucrose solution given the Examiner's finding that it is conventional in the art to change the size and shape of such container (Ans. 6-7 (citing to the secondary references in support of this finding)). (*See* Rep. Br. 2-4.) Similarly, Appellant has not persuaded us that the Examiner erred in finding it is conventional in the art to package a specific quantity of a food or medication in a single use

container, a portion of which may be discarded after the required amount is administered (*see* Ans. 13). Appellant has not identified, nor do we find, any disclosure which supports Appellant's contention that Lazure "critically focuses on administering the entire contents of the unit dose container" (Rep. Br. 10).

Issue 2: Did the Examiner improperly rely on non-analogous art in reaching the conclusion of obviousness?

Appellant contends the Examiner impermissibly relied on a combination of nonanalogous art because "[o]ne of ordinary skill in the children's medical device art would not be likely to reference the container art to find an answer to the problem at hand." (App. Br. 10.)

To render an invention obvious, the prior art does not have to address the same problem addressed by a patent applicant. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 420 (2007). A reference in a different field from that of the inventor's endeavor is still reasonably pertinent if the matter with which it deals "logically would have commended itself to an inventor's attention in considering his problem." *In re Clay*, 966 F.2d 656, 659 (Fed. Cir. 1992). "References are selected as being reasonably pertinent to the problem based on the judgment of a person having ordinary skill in the art." *In re Kahn*, 441 F.3d 977, 986-87 (Fed. Cir. 2006).

The prior art problem addressed by the invention is identified as the lack of a convenient, safe method for sucrose delivery. (App. Br. 7; *see also*, Declaration of Catherine Bush, Ex. B, ¶ 5; Declaration of Don Granger, Ex. C, ¶ 6.) The Examiner found (Ans. 5), and Appellant does not dispute (*see generally*, Rep. Br.), that a sucrose solution is a "sugar solution [that] is edible, but also plays a medicinal role." Thus, in our view, the

Examiner reasonably determined that one of ordinary skill in the art would have considered prior art directed both to sucrose solutions and to methods of conveniently packaging foods and medicines for subsequent use, as relevant to the identified problem (*see* Ans. 5-7). While Appellant has produced declaration evidence to establish that "the state of the art was to hand-mix sucrose in an on-site kitchen or pharmacy" (App. Br. 10-11), Appellant has not directed us to evidence which refutes the Examiner's finding that the ordinary artisan would not have limited his field of search to children's medical devices, but would have also considered the food and pharmaceutical container art. (*See* Ans. para. bridging 10-11.)

Issue 3: Did the Examiner fail to properly identify motivation to combine the references in the manner claimed?

Appellant argues the Examiner failed to properly identify "any suggestion, motivation, or other obvious rationale to combine the[] references." (App. Br. 11.)

> [A]n implicit motivation to combine exists not only when a suggestion may be gleaned from the prior art as a whole, but when the "improvement" is technology-independent and the combination of references results in a product or process that is more desirable, for example because it is stronger, cheaper, cleaner, faster, lighter, smaller, more durable, or more efficient. Because the desire to enhance commercial opportunities by improving a product or process is universal – and even common-sensical – we have held that there exists in these situations a motivation to combine prior art references even absent any hint of suggestion in the references themselves. In such situations, the proper question is whether the ordinary artisan possesses knowledge and skills rendering him *capable* of combining the prior art references.

Dystar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co., 464 F.3d 1356, 1368 (Fed. Cir. 2006).

The Examiner identified the motivation for combining the applied prior art as being a desire to improve upon drawbacks/limitations inherent in any food or medicinal product, namely time-savings in pre-preparing the product, greater convenience in prepackaging individual doses and improved sanitation through aseptic packaging. (Ans. 12.) The Federal Circuit has identified such reasons as providing proper motivation to combine prior art teachings under 35 U.S.C. § 103(a). *See Dystar*, 464 F.3d at 1368. Appellant has not established that the ordinary artisan at the time of the invention did not possess sufficient knowledge and skills to enable him to make the Examiner's proposed combinations/modifications. Therefore, Appellants' general assertions of lack of motivation to combine fail to persuade us of error in the Examiner's obviousness determination.

Issue 4: Did the Examiner properly evaluate Appellant's evidence of non-obviousness along with all the facts on which the prima facie case was reached in concluding that a preponderance of the evidence weighs in favor of obviousness?

Appellant argues the Examiner failed to properly take account of the "compelling evidence of competitor adulation for the invention, commercial success of the invention, and long-felt but unmet need for the invention." (App. Br. 14.) Appellant further contends that "[n]othing in the record indicates that the Examiner ever considered the totality of the rebuttal evidence as a whole. . . . Instead, for each category of such rebuttal evidence, the record is clear that the Examiner simply analyzed it alone and

discounted it as being insufficient to rebut what the Examiner considered to be the *prima facie* case." (App. Br. 21; Rep. Br. 7.)

When rebuttal evidence[1] is provided, the prima facie case dissolves, and the decision is made on the entirety of the evidence. *In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992). However, "evidence of secondary considerations does not always overcome a strong prima facie showing of obviousness." *Asyst Technologies, Inc. v. Emtrak, Inc.*, 544 F.3d 1310, 1316 (Fed. Cir. 2008) (citations omitted).

Evidence of commercial success must be within the relevant market. *Kansas Jack, Inc. v. Kuhn*, 719 F.2d 1144, 1150-51 (Fed. Cir. 1983). "[A]sserted commercial success of the product must be due to the merits of the claimed invention beyond what was readily available in the prior art." *Asyst Technologies,* 544 F.3d at 1316 (quoting *J.T. Eaton & Co. v. Atl. Paste & Glue Co.*, 106 F.3d 1563, 1571 (Fed. Cir. 1997)); *see also*, *Ormco Corp. v. Align Tech., Inc.*, 463 F.3d 1299, 1312 (Fed. Cir. 2006) ("[I]f the feature that creates the commercial success was known in the prior art, the success is not pertinent.").

"[L]ong-felt need is analyzed as of the date of an articulated identified problem and evidence of efforts to solve that problem." *Tex. Instruments v. U.S. Int'l Trade Comm'n*, 988 F.2d 1165, 1178 (Fed. Cir. 1993) (cited in *Perfect Web Technologies, Inc. v. InfoUSA, Inc.*, 587 F.3d 1324, 1332-33 (Fed. Cir. 2009)). Once market forces have created a demand for a product, the relevant inquiry is whether the inventive approach would have presented any technical challenge to one of ordinary skill in the art. *See Friskit, Inc. v.*

[1] *See In re Mehta*, 347 F.2d 859, 866 (CCPA 1965) (treating an unsworn exhibit as argument).

Real Networks, Inc., 306 Fed. Appx. 610, 618 (Fed. Cir. 2009) (citing *Orthopedic Equip. Co. v. United States*, 702 F.2d 1005, 1013 (Fed. Cir. 1983) ("[T]he fact that the two disclosed apparatus would not be combined by businessmen for economic reasons is not the same as saying that it could not be done because skilled persons in the art felt that there was some technological incompatibility that prevented their combination. Only the latter fact is telling on the issue of nonobviousness."); *KSR*, 550 U.S. at 417 (2007) (cautioning against rewarding obvious variations precipitated by "design incentives and other market forces"); *Joy Technologies, Inc. v. Manbeck*, 751 F.Supp. 225, 232 (D.D.C. 1990), *aff'd*, 959 F.2d 226 (Fed. Cir. 1992) (experts' expressed skepticism was entitled to little weight as evidence of nonobviousness because it "was directed to economic and commercial factors, not the technical merit of [the claimed invention]")).

We have carefully reviewed the Examiner's Answer and cannot agree with Appellant's assessment of the Examiner's treatment of the evidence of secondary considerations.

As indicated on pages 12-14 of the Answer, all Declarations, and evidence discussed therein, were considered by the Examiner. Based on a thorough consideration of this evidence, the Examiner determined that the "commercial success and long felt need showings [we]re not convincing; they rely on expected (not unexpected) results; and when measured versus the art taken as a whole do not outweigh the strong case of prima facie obviousness." (Ans. 14.)

Although the SWEET-EASE product was commercially successful, Appellant's evidence fails to establish that the success was due to the merits of the claimed invention beyond what was readily available in the prior art,

e.g., conventional formulations of sweet solutions (Spec. 3, ll. 3-4). Ms. Bush compares sales of SWEET-EASE with those of a completely unrelated type of product. (Bush Decl. ¶¶ 3 and 4.) Moreover, Ms. Bush does not appear to be a completely disinterested individual. At the time of her declaration, she was "employed with Children's Medical Ventures, LLC (indirectly, a wholly owned subsidiary of Respironics, Inc." (Bush Decl. ¶ 1.) The Real Party in Interest is RIC Investments, LLC, also a subsidiary of Respironics, Inc. (App. Br. 4.)

Granger, Guttenberg, and Yohannan, board-certified neonatologists, testified that they had "personally seen" the commercial success of SWEET-EASE in the marketplace (Granger Decl. ¶ 3; Declaration of Neal Guttenberg, Ex. C, ¶ 3; Declaration of M. David Yohannan, Ex. C, ¶ 3) and witnessed an "unexpected" degree of calming effect upon administration of the product (*Id.* ¶ 8). However, it is not apparent that that the unexpected success/effectiveness was due to the claimed product/process rather than to the known, prior art sucrose solution. Each of these three declarants also testified that "[t]here has long been a definite need in our industry for some way to calm and sooth these newborns." (*Id.* ¶ 7). Yet, there is no evidence that others attempted to solve this problem, but failed to do so.

With respect to the TootSweet advertisement, we note that the Declarants fail to mention this product and Appellant has not directed us to any evidence which establishes that Appellant's claims read on the advertised product. Nor is there evidence that Hawaii Medical is a competitor. In this regard, we note that the case law relied upon by Appellant holds that an "infringer's" recognition of a product's value is relevant to a determination of nonobviousness. (*See* App. Br. 14-16.)

Because the record insufficiently indicates that the TootSweet advertisement qualifies as such "evidence," Appellant has not persuaded us that the Examiner erred in failing to consider this article as persuasive "adulation evidence" (Rep. Br. 6-7) or evidence of commercial success (*see* App. Br. 16).

As explained by our reviewing court in *Ritchie v. Vast Resources, Inc.*, 563 F.3d 1334, 1337 (Fed. Cir. 2009):

> Among the inventions that the law deems obvious are those modest, routine, everyday, incremental improvements of an existing product or process that confer commercial value (otherwise they would not be undertaken) but do not involve sufficient inventiveness to merit patent protection. This class of inventions is well illustrated by efforts at routine experimentation with different standard grades of a material used in a product-standard in the sense that their properties, composition, and method of creation are well known, making successful results of the experimentation predictable.

CONCLUSION

Appellant has not persuaded us that the Examiner erred in concluding that a preponderance of the evidence weighs in favor of obviousness. The decision of the Examiner rejecting claims 1-4, 6, 7, 10, 12, 13, 15-17, and 19-39 is affirmed.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1).

AFFIRMED

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